

REMARKS

I. Examiner Interview

Applicant would like to thank the Examiner and Supervisor for the courtesies extended during the Examiner Interview conducted on December 14, 2010. During the Examiner Interview, the inventor Jennifer Southgate described the following as background to the technology: typical cell culture protocols for propagation of cells compared to protocols for differentiation; rat urothelium cell culture protocols are not directly applicable to human urothelium cell culture protocols; and the alleged "differentiation marker" in Zhang is actually not a differentiation marker but is a marker indicative of over-proliferation of cells. The Applicant's representative then discussed the legal arguments of non-obviousness of the pending claims, which include the following: the combination of Cross et al (2001) and Zhang et al (2001) is invalid as there is no valid reason to combine the teachings of Cross & Zhang; there is no reasonable expectation of success in using rat urothelium cell culture protocols for human urothelium, and thereby the combination of references does not satisfy a *prima facie* case of obviousness; and even if combined, the combined teachings of Cross and Zhang does not teach the presently claimed method that obtains a stratified/terminally-differentiated human urothelial model. The Examiner and Supervisor agreed with Applicant to the following: Zhang does not teach or suggest that rat urothelium cell culture protocols are applicable to human urothelium cell culture protocols; the CM-KSFM media of Zhang is not equivalent to serum containing media; Zhang does not teach or suggest cell culture protocols that use serum containing medium and result in stratified, differentiated rat urothelium; Zhang does not teach or suggest that the so called "Serum/Redispersal/Serum" steps of the present invention results in stratified, differentiated rat urothelium; and growth, expansion, or proliferation of cells is not equivalent to differentiation. Moreover, the Examiner and Supervisor agreed that the combination of Zhang and Cross was improper, and does not establish a *prima facie* case of obviousness with regard to the presently pending claims, which are not amended by this paper.

II. Background

The present amendment and remarks are in response to the Office Action mailed August 27, 2010. Claims 13, 15-26 and 29-35 are remain pending and unchanged for consideration on the merits.

III. Rejection on the Merits

A. 35 USC § 103

The Office Action rejects claims 13, 15-19, 21, 23-26, and 29-35 under 35 USC § 103(a) as being obvious over *Cross et al.* (Biochemical Society Transactions 2001) in view of *Zhang* (In Vitro Cell. Dev Biol.-Animal (2001)). The Office Action also rejects claim 16 under 35 USC § 103(a) as being obvious over *Cross et al.* in view of *Zhang* as applied above and further in view of *Seijiro et al.* (US 4,654,304) and *Jefferson et al.* (US 5,380,660). Additionally, the Office Action rejects claims 20 and 22 under 35 USC § 103(a) as being obvious over *Cross et al.* in view of *Zhang* as applied above and further in view of *Judd et al.* (US 6,692,961) Applicant respectfully asserts that the Office Action has not established a *prima facie* case of obviousness because of at least the following: there is no valid reason to combine *Cross* and *Zhang*; there is no reasonable expectation of success in using rat urothelium cell culture protocols for human urothelium; and the combination of *Cross* and *Zhang* does not teach or suggest each and every element of the currently pending independent claims.

As recited above with regard to the Examiner Interview, the Examiner and Supervisor agreed that: *Zhang* does not teach or suggest that rat urothelium cell culture protocols are applicable to human urothelium cell culture protocols; the CM-KSFM media of *Zhang* is not equivalent to serum containing media; *Zhang* does not teach or suggest cell culture protocols that use serum containing medium and result in stratified, differentiated rat urothelium; *Zhang* does not teach or suggest that the so called "Serum/Redispersal/Serum" steps of the present invention results in stratified, differentiated rat urothelium; and growth, expansion, or proliferation of cells is not equivalent to differentiation. Additionally, the Examiner and Supervisor agreed that the combination of *Zhang* and *Cross* was improper, and does not establish a *prima facie* case of obviousness with regard to the presently pending claims 13, 24, and 34.

With regard to the rejection of claim 16, neither *Seijiro* nor *Jefferson* nor the combination thereof cures the deficiencies of the combination of *Cross* and *Zhang* recited above with regard to claim 13 from which claim 16 depends. Particularly, there is no valid motivation to make the combination of *Cross*, *Zhang*, *Seijiro* and *Jefferson*, and such combination still does not teach or suggest each and every element of the currently pending claims. Therefore, claim 16 is allowable and non-obvious for the same reasons claim 13 is allowable and non-obvious.

With regard to the rejection of claims 20 and 22, *Judd* does not cure the deficiencies of the combination of *Cross* and *Zhang* recited above with regard to claim 13 from which claims 20 and 22 depend. Particularly, there is no valid motivation to make the combination of *Cross*, *Zhang*, and *Judd*, and such combination still does not teach or suggest each and every element of the currently pending claims. Therefore, claims 20 and 22 are allowable and non-obvious for the same reasons claim 13 is allowable and non-obvious.

In view of the foregoing, a *prima facie* case of obviousness has not been established with respect to the currently pending claims. Thus, Applicant respectfully requests withdrawal of the rejection of claim under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made regarding the cited art or the pending application, including any Official Notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in any action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as the required motivation or suggestion to combine the relied upon Notice with the other art of record.

Applicant believes claims 13, 15-26 and 29-35 are in allowable form as discussed above. As such, Applicant respectfully requests reconsideration of the application and allowance of presently pending claims.

In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney by telephone at (801) 533-9800. If a minor Examiner Amendment is necessary for allowance of the claims, Applicant respectfully requests contacting the undersigned attorney so that a possible Examiner Amendment can be discussed.

Dated this 17th day of December 2010.

Respectfully submitted,

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